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Golden

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[54] PRELUBRICATED URINARY CATHETER AND PACKAGE ASSEMBLY

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[52] U.S. Cl. 206/210; 53/428; 206/364

[58] Field of Search 206/205, 210, 363, 364, 206/438, 803; 53/428

[56] References Cited

U.S. PATENT DOCUMENTS

3,648,704	3/1972	Jackson	206/364
3,750,875	8/1973	Juster	206/364
3,794,042	2/1974	De Klotz et al.	206/210
3,854,483	12/1974	Powers	206/210
3,934,721	1/1976	Juster et al.	206/364

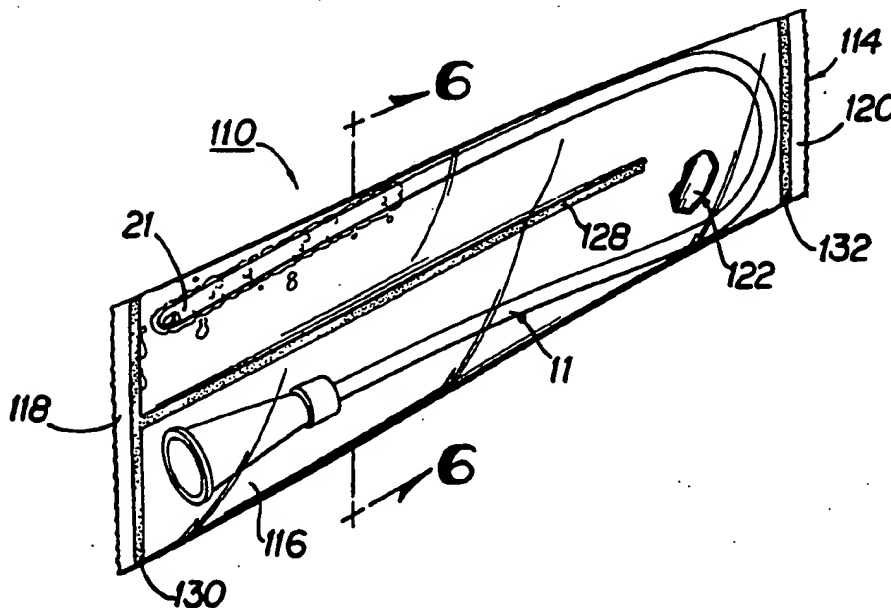
3,967,728	7/1976	Gordon et al.	206/210
3,978,983	9/1976	Brezette	206/210
4,772,275	9/1988	Erllich	206/364
4,811,847	3/1989	Reif et al.	206/210
4,923,061	5/1990	Trombley, III	206/364
5,131,537	7/1992	Gonzales	206/364

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[57] ABSTRACT

A prelubricated urinary catheter and package assembly for use in draining the bladder through the urethra comprising an elongate catheter tube with a lubricant on the projecting end thereof and a package assembly receiving the catheter therein an arrangement for isolating the lubricant on the projecting end of the catheter from the rest of the catheter in the catheter receiving cavity.

5 Claims, 2 Drawing Sheets



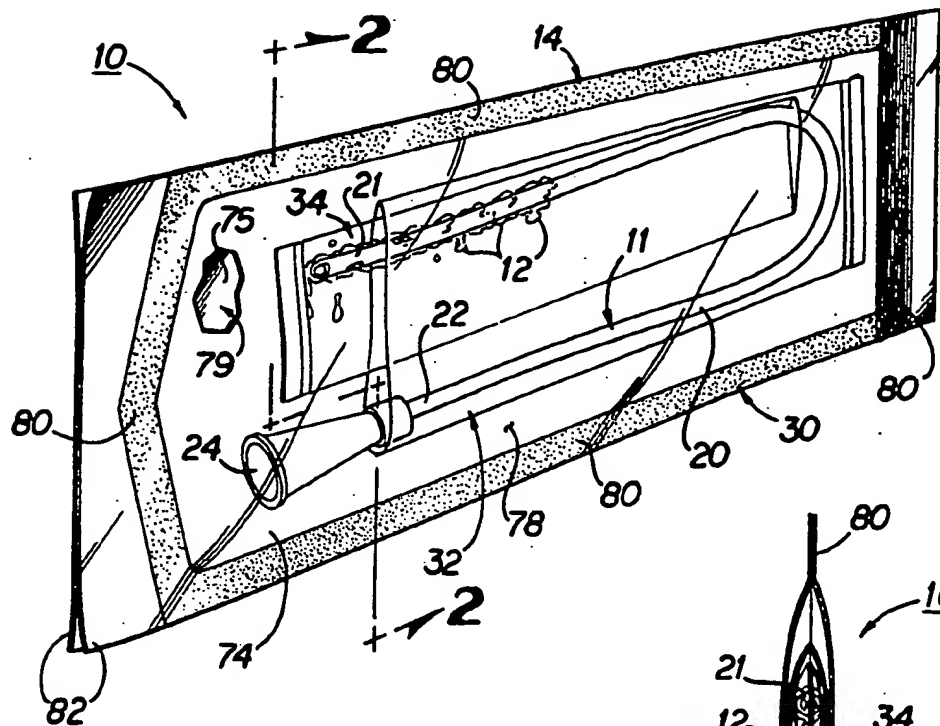


FIG 1

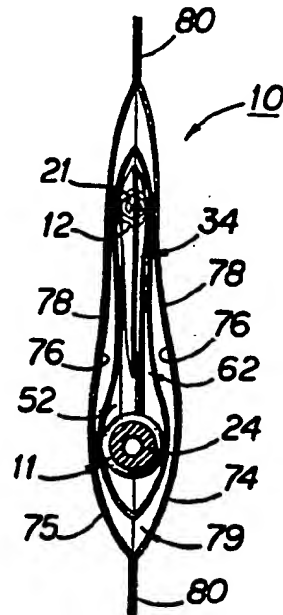


FIG 2

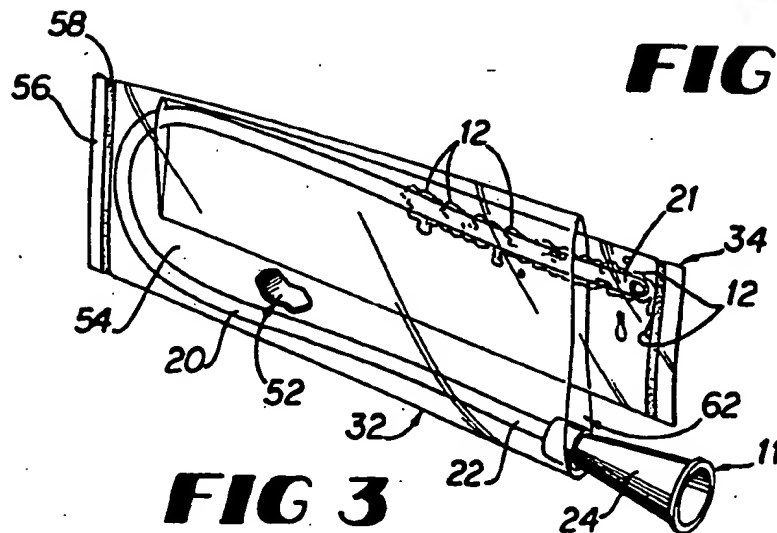
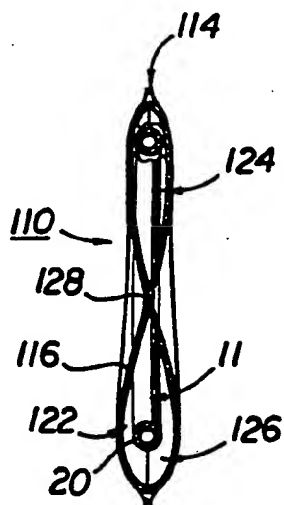
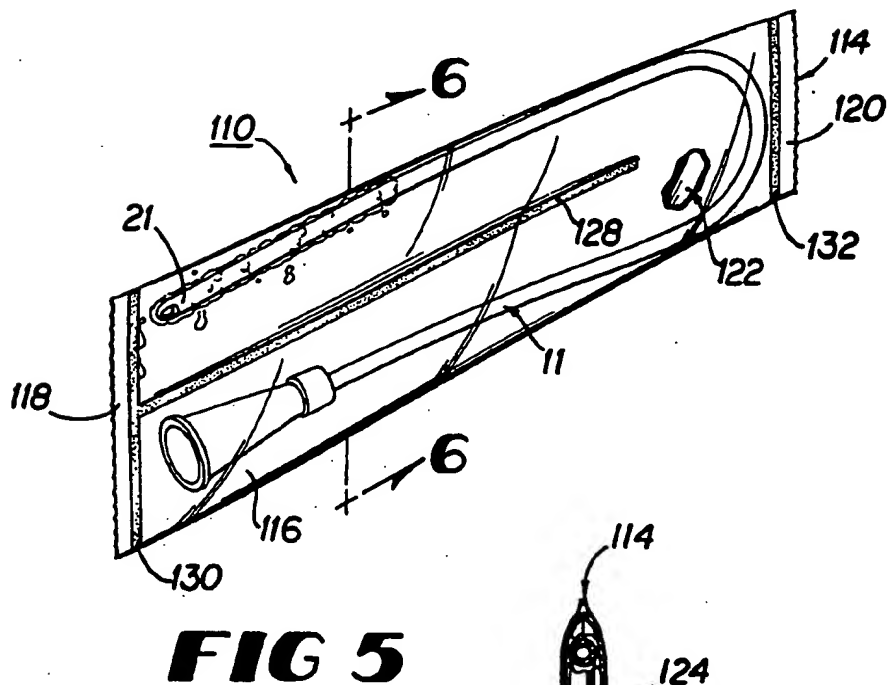
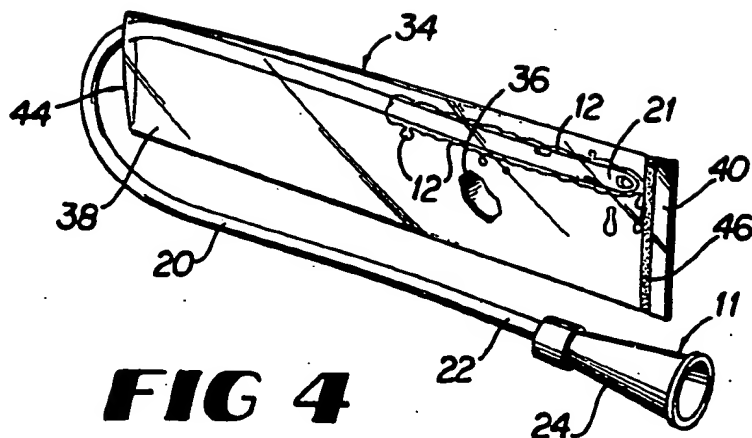


FIG 3



PRELUBRICATED URINARY CATHETER AND PACKAGE ASSEMBLY

BACKGROUND OF THE INVENTION

This invention relates generally to catheters and more particularly to prelubricated intermittent catheters.

Heretofore, single use catheters designed for intermittent or self catheterization have been supplied without an insertion lubricant thereon. This is because the lubricant is designed to liquify at body temperature and frequently becomes sufficiently liquid during storage to coat the inside of the package carrying the catheter and also the complete catheter. As a result, the prior art supplied the lubricant in a separate container. This required the lubricant to be applied by the user after the catheter was removed from the sterile package in which the catheter is supplied. Not only was this inconvenient for the user but also allowed the lubricant in the tube to become contaminated thereby spreading the contamination to subsequently used catheters when the lubricant was applied.

SUMMARY OF THE INVENTION

These and other problems and disadvantages associated with the prior art are overcome by the invention disclosed herein by providing a urinary catheter and package assembly which provides a prelubricated catheter for intermittent use to facilitate the use thereof. The lubricant preapplied to the projecting end of the catheter is isolated from the rest of the catheter and package so that the lubricant coats only the desired portion of the catheter and does not migrate to undesirable portions of the package. In those instances where it is desirable to precoat the entire catheter with lubricant, the catheter is sealed in a single cavity in the package.

The apparatus of the invention is directed to a prelubricated urinary catheter and package assembly for use in draining the bladder through the urethra comprising an elongate catheter tube with a lubricant on the projecting end thereof and a package assembly defining a catheter receiving cavity therein with isolation means for isolating the lubricant on the projecting end of the catheter from the rest of the catheter in the catheter receiving cavity. The package assembly may include a primary receptacle defining a primary catheter receiving cavity therein for stowing the catheter with the isolation means comprising a secondary receptacle defining a secondary projecting end receiving cavity therein receiving the projecting end of the catheter with the lubricant thereon to isolate the lubricant from the primary cavity. Alternatively, the package assembly may include a single catheter receiving cavity receiving the catheter with the isolation means dividing the catheter receiving cavity into first and second portions so that the projecting end of the catheter with the lubricant thereon is housed in the second portion of the cavity and the rest of the catheter is housed in the first portion of the cavity.

These and other features and advantages of the invention will become more clearly understood upon consideration of the following detailed description and accompanying drawings wherein like characters of reference designate corresponding parts throughout the several views and in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of the invention;

FIG. 2 is an enlarged cross-sectional view taken generally along line 2—2 in FIG. 1;

FIG. 3 is a perspective view similar to FIG. 1 with the outside enclosing receptacle removed;

FIG. 4 is a perspective view similar to FIG. 2 with the intermediate primary receptacle removed;

FIG. 5 is a perspective view of a second embodiment of the invention; and,

FIG. 6 is an enlarged cross-sectional view taken generally along line 6—6 in FIG. 5.

These figures and the following detailed description disclose specific embodiments of the invention, however, it is to be understood that the inventive concept is not limited thereto since it may be embodied in other forms.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

Referring to FIG. 1, it will be seen that the catheter and package assembly 10 includes a catheter 11 with a lubricant 12 thereon and a package assembly 14 that carries the catheter therein. The lubricant 12 is preapplied to the catheter 11 so that the user simply has only to remove the catheter 11 from the package assembly 14 for use.

The catheter 11 corresponds to those catheters currently in use for intermittent catheterization. Catheter 11 includes an elongate catheter tube 20 with a projecting end 21 and an opposed drainage end 22. The drainage passage extends through the tube 20 from the projecting end to the drainage end so that once the projecting end 21 enters the bladder, the bladder can drain through the catheter. The drainage end 22 of the catheter tube 20 may be left plain or equipped with a receptacle connector 24 as shown in the figures.

The lubricant 12 is that typically used with catheters and is designed to liquify at body temperature. The lubricant 12 is applied to the catheter tube 20 at the projecting end 21 thereof and a prescribed distance along the catheter tube from the projecting end. The package assembly 14 is designed to prevent the lubricant 12 from completely coating the catheter or completely coating the inside of the package assembly 14 and at the same time to provide a sealed sterile enclosure for the lubricated catheter. Preventing transfer of the lubricant 12 to other portions of the catheter is desirable since the presence of lubricant on portions of the catheter other than the projecting end 21 would cause those surfaces to become slippery and increase the manual dexterity level necessary for proper insertion of the catheter during use.

The first embodiment of the package assembly 14 shown in FIGS. 1-4 includes an outside enclosing receptacle 30, an intermediate primary receptacle 32 and an inside secondary receptacle 34. The secondary receptacle 34 serves as the isolating means to prevent the lubricant 12 flowing away from the projecting end 21 of the catheter 11, the primary receptacle 32 serves to contain the catheter 11 with the secondary receptacle 34 thereon while maintaining the catheter formed in the U-shaped configuration for stowing, yet allowing access thereto, and the enclosing receptacle 30 serves to contain the catheter 11 in the primary and secondary

receptacles 32 and 34 to provide a sterile environment for the catheter until it is used.

The secondary receptacle 34 comprises a secondary tubular sheath 38 with one end 40 closed to define a secondary projecting end receiving cavity 36 therein and with the other end open to define a secondary access opening 44 through which the lubricated projecting end 21 is inserted as seen in FIG. 4. The elongate secondary receptacle 34 serves as a means for isolating the lubricant 12 and lubricated projecting end 21 of the catheter 11 from the rest of the catheter disposed outside of the secondary receptacle 34. The secondary receptacle 34 may be formed from a flexible, heat sealable plastic tubular film with the closed end sealed by secondary heat weld 46. Any convenient alternative construction may be used as long as it defines a cavity into which the projecting end of the catheter will fit, for example, an elongate rigid hollow tube with an open end and a closed end. Prior to insertion of the catheter into the bladder, the lubricated projecting end 21 is removed from the secondary receptacle 34 by sliding it out of the secondary receptacle receiving cavity 36 through the secondary access opening 44. The projecting end thus emerges from the secondary receptacle 34 coated with the lubricant 12 ready for use and leaving a residue of the lubricant within the secondary receptacle 34.

Looking now at FIG. 3, the primary receptacle 32 comprises a primary tubular sheath 54 formed from a flexible heat sealable plastic tubular film with one end 56 closed such as by primary heat weld 58 to form a primary cavity 52 therein and with the opposite end open to define a primary access opening 62 to the primary cavity 52. The primary receptacle 32 enhances the handling of the catheter 11 prior to use by reducing the tendency of the lubricated projecting end to slip out of or rotate within the secondary receptacle 34 and also provides a barrier to prevent contamination of those portions of the catheter not covered by the secondary receptacle 34. The primary receptacle 32 may be sized and shaped to allow the catheter to be stowed in a U-shaped configuration resulting in a catheter unit which is more compact and which may be more easily handled than a package accommodating the catheter in a fully extended configuration. It is to be understood, however, that the particular configuration is not meant to be limiting.

The outside enclosing receptacle 30 comprises a pair of flexible side sheets 74 and 75, with each side sheet having an interior surface 76 and an exterior surface 78 which is more clearly shown in FIG. 2. A peripheral seal 80 is formed around the overlying sheets 74 and 75 and located adjacent to the outer edges of and continuously along the perimeter of the side sheets. This seals the catheter 11 with the lubricant 12 thereon along with the receptacles 32 and 34 in the cavity 79 to complete the assembly 10 so that the contents of the outside receptacle 30 can be sterilized in conventional manner.

The catheter 11 is retrieved from the enclosing receptacle 30 by cutting open the enclosing receptacle and removing the contents. Alternatively, the enclosing receptacle 30 may be fabricated to facilitate being torn open by hand by causing a portion of the seal 80 of each of the side sheets to be disposed a predetermined distance from opposing edges of each side sheet to provide tear pen flaps 82. The enclosing receptacle 30 may be conveniently opened by grasping the tear open flaps 82

and pulling them apart to cause the enclosing receptacle 30 to part along the sealing surfaces 80.

An alternative embodiment of a catheter and packaging assembly designated 110 is shown in FIGS. 5 and 6. The catheter 11 and lubricant 12 are the same as with the first embodiment of the package assembly. The package assembly 114 is changed.

The package assembly 114 comprises a single piece tubular plastic sheath 116 with opposed ends 118 and 120 defining a single catheter receiving cavity 122 therein. The catheter receiving cavity 122 is divided into a projecting end receiving first portion 124 and a discharge end receiving second portion 126 by any suitable means such as a longitudinally extending septum weld 128 joining the sides of the sheath 116 together between the projecting and discharge ends of the catheter. The prelubricated projecting end 21 of the catheter 11 is disposed within the first portion 124 and the rest of the catheter is disposed within the second portion 126 by forming the catheter 11 into a U-shaped configuration. The first end 118 of the tubular sheath 116 is sealed by a first end weld 130. The first end weld 130 is located so that a portion of the first end weld 130 intersects the septum weld 128 and is effective to isolate the lubricant 12 and the lubricated projecting end 21 from the drainage end 22 disposed in the second portion 126 of the catheter receiving cavity 122. The second end 120 of the tubular sheath 116 is also sealed by a second end weld 132 and is effective to complete the sealing of the package assembly 114 so that the entire catheter and package assembly 110 can be sterilized in conventional manner.

The catheter 11 contained in the single piece package assembly 114 may be retrieved by cutting the tubular sheath 116 adjacent to the second end weld 132, grasping the "U" shaped region of the catheter tube 20 and sliding the catheter 11 from the package assembly 114. Of course, the user may open the package assembly 114 in any convenient manner.

In those instances where the complete catheter 11 is to be coated with the lubricant 12, the prelubricated catheter is located in a single cavity in the package assembly. It is still desirable for the cavity carrying the catheter to be subdivided into different portions to keep all of the lubricant from flowing into one part of the cavity.

What is claimed as invention is:

1. A prelubricated urinary catheter and package assembly for use in draining the bladder through the urethra comprising:

a) an elongate catheter tube defining a projecting end and a drainage end at opposite ends thereof and defining a drainage passage extending from said projecting end to said drainage end so that fluids in the bladder can drain therethrough when said projecting end of said catheter tube is inserted into the bladder through the urethra;

b) a lubricant on the projecting end of said catheter; and

c) a package assembly comprising:

a flexible primary receptacle defining a primary catheter receiving cavity therein for stowing said catheter, said primary catheter receiving cavity sized and shaped to stow said catheter in a generally U-shaped configuration;

isolation means comprising a flexible secondary receptacle defining a secondary projecting end receiving cavity therein and a secondary access

5

opening to said secondary receiving cavity removably receiving the projecting end of said catheter with the lubricant thereon to isolate the lubricant from said primary cavity, said secondary receptacle removable from the projecting end of said catheter without removing the lubricant from said catheter,

said primary receptacle defining a primary access opening to said primary cavity so that said catheter and said secondary receptacle with the projecting end of said catheter therein can be removably inserted into said primary cavity in said primary receptacle; and

an enclosing receptacle defining a sterile cavity sealably receiving said primary and secondary receptacles and said catheter with the lubricant thereon therein.

2. A prelubricated urinary catheter and package assembly for use in draining the bladder through the urethra comprising:

- a) an elongate catheter tube having a projecting end and an opposite end and defining a drainage passage extending therethrough so that fluids in the bladder can drain therethrough when said projecting end of said catheter tube is inserted into the bladder through the urethra;
- b) a lubricant on said projecting end of said catheter; and
- c) a package assembly including:
 - a thin flexible tubular sheath having opposed sides defining a catheter receiving cavity therein sized to hold said catheter tube in a U-shaped configuration and in which said catheter with said lubricant thereon is housed in the U-shaped configuration, and
 - a septum weld sealing said sides of said tubular sheath together between the ends of the catheter

6

so as to isolate the lubricated projecting end of the catheter from the rest of the catheter.

3. The assembly of claim 2 wherein said package assembly wherein said catheter receiving cavity has opposed ends and further includes an end weld connected to said septum weld and sealing said sides of said tubular sheath together to seal one of the ends of said catheter receiving cavity.

4. A method of packaging catheters comprising the steps of:

- a) applying a lubricant to the projecting end of the catheter and not to the drainage end of the catheter; and,
- b) enclosing the catheter in a package assembly so that the lubricant and the projecting end of the catheter is isolated from the rest of the catheter to limit the area of the catheter coated with lubricant while in the package assembly, and further comprising the substeps of:
 - b1) forming the catheter in a U-shaped configuration,
 - b2) inserting the catheter in the U-shaped configuration into a tubular plastic sheath, and
 - b3) heat sealing the sides of the plastic sheath together between the ends of the catheter so as to isolate the lubricated projecting end of the catheter from the rest of the catheter.

5. The method of claim 4 wherein step b) comprises the further substeps of:

- b4) heat sealing the opposite ends of the plastic sheath to seal the catheter in the plastic sheath while locating one of the end heat seals so that it intersects the heat seal formed in substep b3) to help isolate the lubricated projecting end of the catheter from the rest of the catheter.

* * * * *

United States Patent [19]

Utas-Sjöberg

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[54] CATHETER PACKAGE

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[**] Term: 14 Years

[21] Appl. No.: 10,141

[22] Filed: Feb. 2, 1987

[30] Foreign Application Priority Data

Aug. 11, 1986 [SE] Sweden 861827

[52] U.S. Cl. D24/54

[58] Field of Search D24/54; 206/364, 571, 206/572, 438, 484; 604/171, 172, 199

[56] References Cited

U.S. PATENT DOCUMENTS

D. 236,325 8/1975 Miller D24/54 X

3,750,875 8/1973 Juster 604/172 X
3,967,728 7/1976 Gordon et al. 206/364
4,091,922 5/1978 Egler 604/171 X

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[57] CLAIM

The ornamental design for a catheter package, as shown.

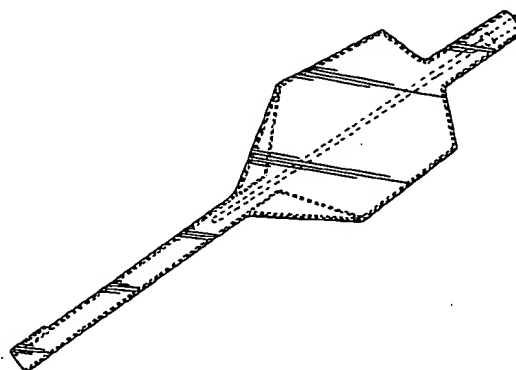
DESCRIPTION

FIG. 1 is an elevational view of a catheter package, showing my new design, the opposite side elevational view being identical thereto and a catheter being shown in broken lines for illustrative purposes only and forming no part of the claimed design;

FIG. 2 is an elevational view thereof, with the catheter removed; and

FIG. 3 is an edge view.

The broken lines along the periphery of the claimed invention in FIGS. 1 and 2 are seams.



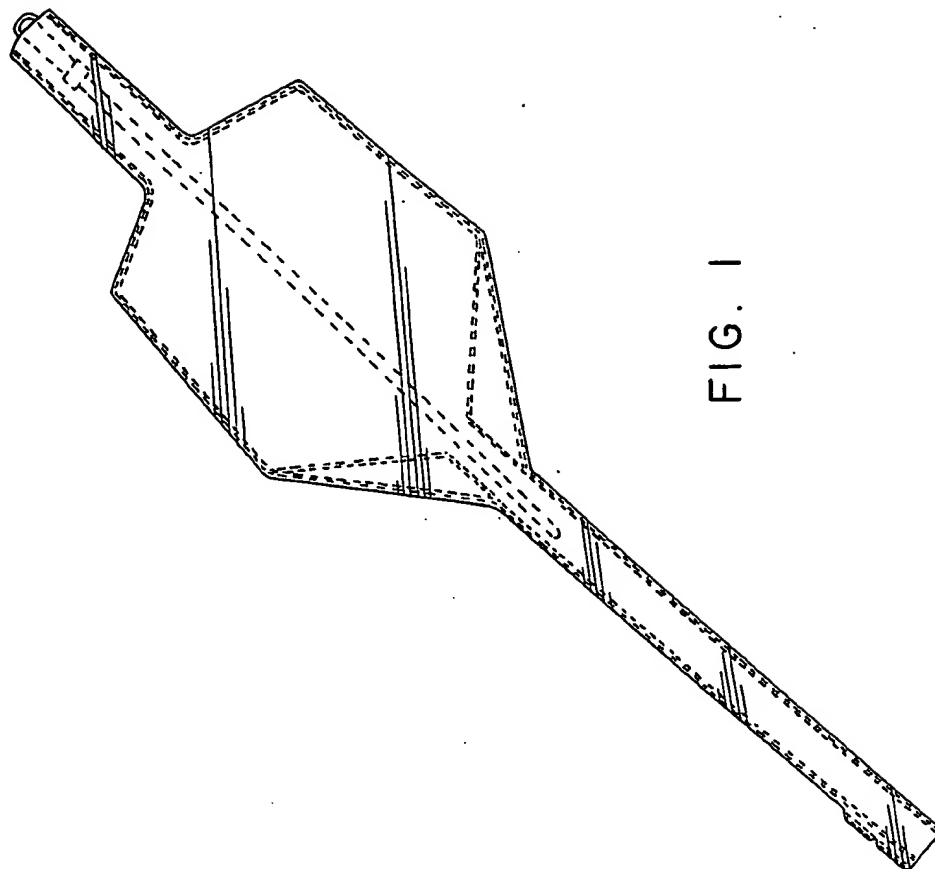


FIG. 1

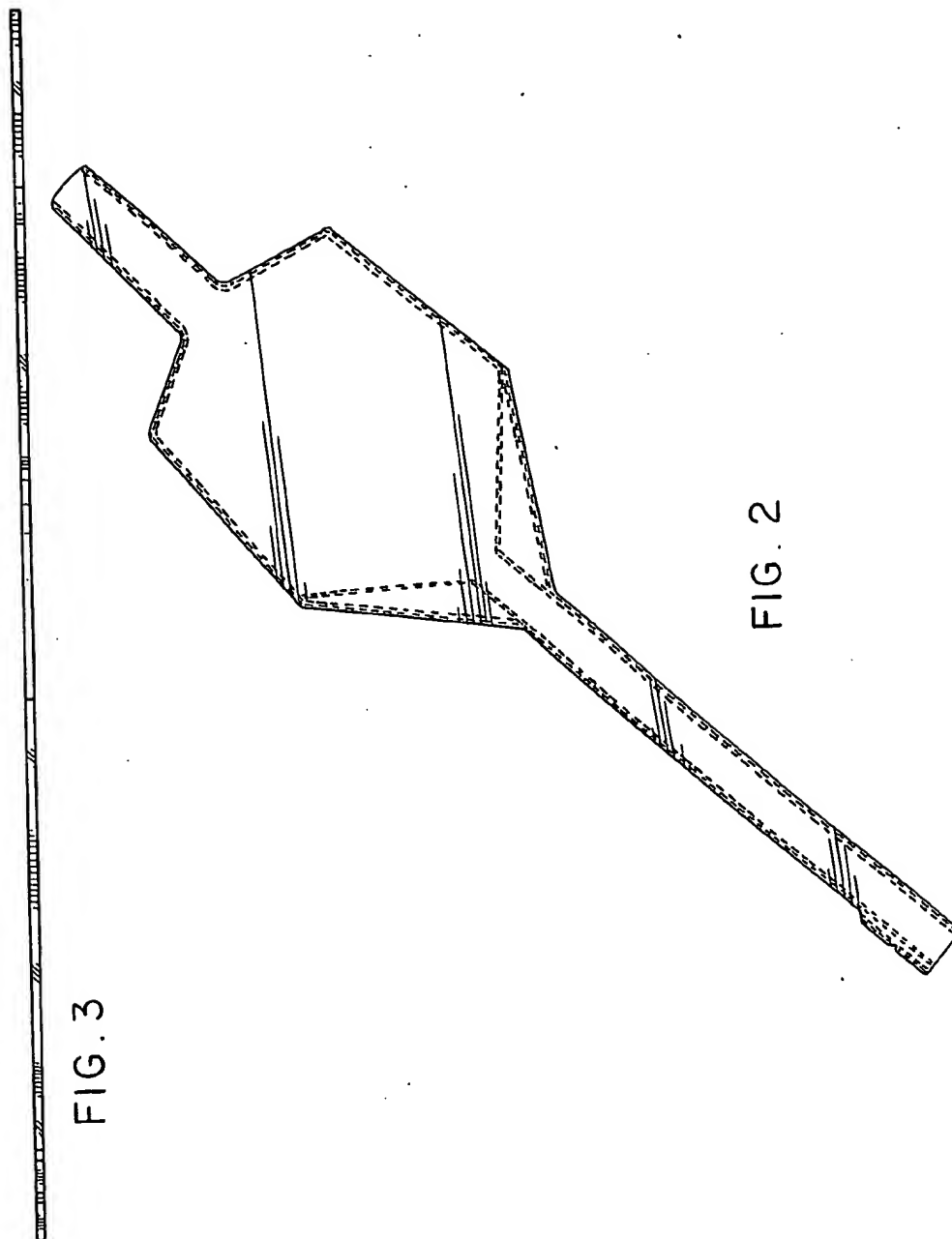


FIG. 3

FIG. 2

[54] **METHOD OF SHEATHING CATHETER**

[75] **Inventor:** Knute D. Jackson, McHenry, Ill.
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[22] **Filed:** Jul. 13, 1977

[51] **Int. Cl.²** A61M 25/00; B65B 5/04
[52] **U.S. Cl.** 53/473; 53/459;
128/349 R; 29/433; 206/363
[58] **Field of Search** 128/349 R, 349 B, 349 BV,
128/348; 206/363, 364, 438, 443, 306; 229/87.2;
53/459, 473; 29/433

[56]

References Cited

U.S. PATENT DOCUMENTS

3,112,031	11/1963	Stewart	128/349 R
3,347,450	10/1967	Godwin	229/87.2
3,749,237	7/1973	Dorton	206/438
3,750,875	8/1973	Juster	128/349 R X
3,934,721	1/1976	Juster et al.	128/349 R X
3,967,726	7/1976	Roeser	206/306

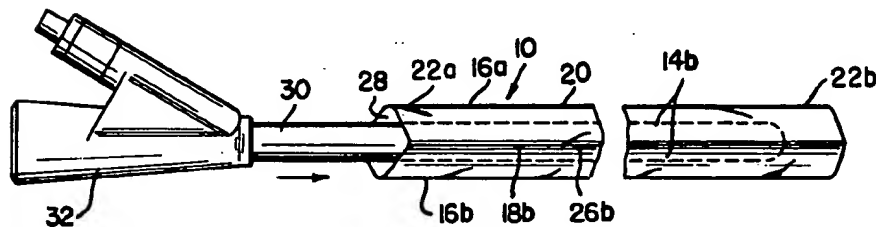
Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Powell L. Sprunger

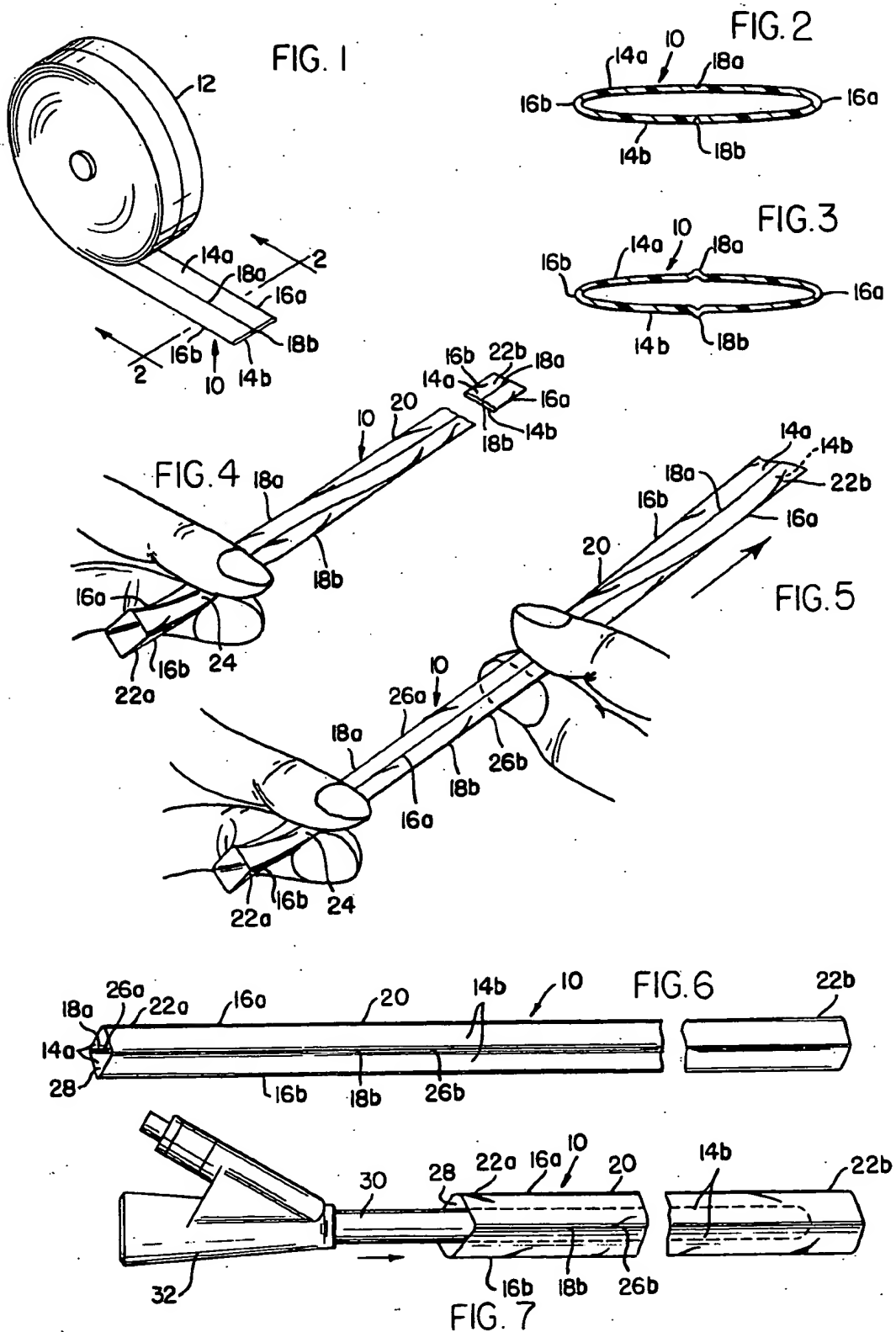
[57]

ABSTRACT

A catheter having an elongated folded sleeve of flexible material closely received on a shaft of the catheter. A method is provided for placement of the sleeve on the catheter shaft.

4 Claims, 7 Drawing Figures





METHOD OF SHEATHING CATHETER

BACKGROUND OF THE INVENTION

The present invention relates to catheter assemblies, and more particularly to protective coverings for catheters.

An assortment of catheters have been proposed in the past for use on patients. In most cases such catheters must be available in a sterile condition at the time of use, and, accordingly, they are placed in suitable packages which are subjected to sterilization procedures in order to render the packaged catheter aseptic. In addition, it is desirable to further protect the shafts of certain catheters, such as Foley or urinary catheters, in the package. This follows since such catheters may develop static electricity and their shafts may attract lint or dust when the package is opened at the time of use, and since it is desirable to protect the catheter shafts from contamination during handling.

It would thus be desirable to place a sheath or sleeve of plastic material over the catheter shaft in order to accomplish this purpose. However, such a procedure has been found to be very difficult in practice, since the usual material of the sleeves provides an undue amount of friction and resistance against placement of the usual catheter shaft between the closely spaced walls of the sleeve, e.g. a sleeve made from a low density polyethylene and a catheter made from latex or a silicone material. Normally, placement of such a sleeve over the catheter shaft has been carried out by hand, and it has been found extremely difficult to insert such a catheter shaft into a sleeve which would fit relatively snugly about the shaft. Accordingly, it has been found necessary to use sleeves which have an unduly large size relative the diameter of the catheter shaft, although the covering procedure is still tedious when attempted without the aid of accessory devices, such as blowing machines to open the sleeves.

SUMMARY OF THE INVENTION

A principal feature of the present invention is the provision of an improved catheter assembly which may be formed in a simplified manner.

The catheter assembly of the invention comprises, a sleeve of flexible material received on the shaft. The sleeve has first and second walls extending between a pair of opposed first longitudinal folds, with each of the first and second walls having a longitudinal second fold located intermediate the first folds.

A feature of the invention is that the sleeve has inner dimensions slightly larger than the outer dimensions of the catheter shaft, such that the shaft is relatively snugly received within the sleeve.

Another feature of the invention is that the first and second walls are creased along longitudinally extending first and second lines in order to modify the sleeve from a generally flat to an open configuration.

A further feature of the invention is that the catheter shaft may be readily inserted into the sleeve while in the open configuration.

Still another feature of the invention is that in a preferred form the first and second lines may be located along lines of weakness in the first and second walls, such that the walls may be readily folded along the lines during placement of the catheter.

Yet another feature of the invention is that the sleeve may be twisted slightly to place the lines in the twisted

portion at opposed sides of the sleeve and to facilitate folding of the sleeve along the lines.

Further features will become more fully apparent in the following description of the embodiments of this invention and from the appended claims.

DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a perspective view of a roll of an elongated sleeve in a generally flat configuration;

FIG. 2 is a sectional view taken substantially as indicated along the line 2—2 of FIG. 1;

FIG. 3 is a sectional view of another embodiment of the sleeve for use in placement over a catheter shaft according to a method of the present invention;

FIG. 4 is a fragmentary perspective view of a sleeve being twisted in a portion according to a method of the present invention;

FIG. 5 is a perspective view of the sleeve as being folded along longitudinal lines according to a method of the present invention;

FIG. 6 is a fragmentary perspective view of the sleeve after a folding operation according to the present invention; and

FIG. 7 is a fragmentary perspective view illustrating a catheter shaft as partially inserted into the folded sleeve.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIGS. 1 and 2, there is shown an elongated sleeve generally designated 10 of flexible material as wound into the configuration of a roll 12. The sleeve or shield 10 may be made of any suitable material, such as low or high density polyethylene, and in a preferred form is transparent. As shown, the sleeve 10 maintains a generally flat configuration when unwound from the roll 12, and has a pair of closely spaced opposed first and second walls 14a and 14b, respectively, extending between a pair of opposed longitudinal fold lines 16a and 16b, respectively, which connect the walls 14a and b. The walls 14a and b have longitudinal lines of weakness 18a and 18b, respectively, with the weakness lines 18a and b being generally aligned and located generally centrally intermediate the opposed folds 16a and b. In a suitable form, the weakness lines 18a and b may comprise longitudinal lines of reduced thickness in the walls 14a and b which may also serve as rupture or tear lines for the sleeve 10 during use. In an alternative form, as shown in FIG. 3, the weakness lines 18a and b may comprise pre-folds of the walls along fold lines 18a and b which extend longitudinally in the sleeve 10. If desired, the sleeve 10 may have lines of reduced thickness coinciding with the fold lines 16a and b at the edges of the sleeve. As will be seen below, the width of the walls 14a and b between the fold lines 16a and b is selected such that the sleeve 10 closely fits an associated catheter shaft when the sleeve covers the shaft, i.e., the placed sleeve 10 has inner dimensions slightly larger than the outer dimensions or diameter of the catheter shaft.

The sleeve 10 may be placed on the catheter shaft according to a method of the present invention which is described as follows. With reference to FIGS. 1 and 4, an end portion of the sleeve 10 may be unwound from the roll 12, and a segment 20 having end portions 22a and 22b and a length approximately equal to the length

3

f the catheter shaft may be severed from the roll. With reference to FIG. 4, an end portion 24 of the sleeve 10 may be twisted slightly in order to position the lines of weakness 18a and b in the twisted portion 24 at the sides

f the sleeve 10. Next, with reference to FIG. 5, the portion 24 of the sleeve 10 is retained by the fingers in the twisted configuration while the remainder of the sleeve 10 is creased or folded along the length of the weakness lines 18a and b intermediate the twisted portion 24 and the opposed sleeve ends 22a and b. After the folding operation has been completed the sleeve may be released, and the creases or fold lines along the weakness lines 18a and b, in addition to fold lines 16a and b, cause the sleeve walls to become separated. Thus, as shown in FIG. 6, the sleeve 10 assumes an open configuration and defines a cavity 28 of generally square cross-sectional shape between the sleeve walls 14a and b. Finally, with reference to FIG. 7, the shaft 30 of a catheter 32, such as a Foley catheter which may be made of latex or a silicone material, may be readily inserted into the cavity 28 of the creased sleeve 10 while the sleeve 10 is in the open configuration.

In accordance with the present invention, the sleeve 10 is creased along the weakness lines 18a and 18b in order to transform the sleeve from a generally flat to an open configuration, after which the catheter shaft 30 may be inserted into the cavity 28 of the folded sleeve 10. The sleeve may be readily placed on a catheter shaft having outer dimensions slightly less than the inner dimensions of the sleeve, e.g., a sleeve 10 having a width between folds 16a and b of approximately $\frac{1}{8}$ inches may be easily placed on a catheter shaft having a diameter of approximately $\frac{1}{4}$ inches when carried out according to the method of the present invention, thus permitting simplified covering of a catheter shaft by a relatively snug sleeve which would otherwise be extremely difficult. The covered catheter may then be placed in a suitable package which is sterilized preparatory to use. After the package has been opened at the

4

time of use, the sleeve 10 protects the catheter shaft from contamination during handling, and prevents the accumulation of dust or lint on the shaft in the event that the catheter should develop static electricity.

The foregoing detailed description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

I claim:

1. A method of covering an elongated limp cylindrical catheter shaft of generally uniform diameter with an elongated sleeve of non-rigid flexible plastic material having opposed first and second walls extending between a pair of opposed folds defining a generally flat configuration of the sleeve, and having a high coefficient of friction relative to the catheter shaft, comprising the steps of:

creasing said first and second walls along longitudinally extending first and second lines respectively located in said first and second walls generally centrally between said opposed folds while modifying the sleeve from said generally flat to an open configuration of square cross section having inner side dimensions slightly larger than the diameter of said catheter shaft to facilitate insertion of said catheter shaft into said sleeve; and inserting the catheter shaft between the walls of the sleeve while in said open configuration.

2. The method of claim 1 wherein said creasing step comprises the step of folding said first and second walls along lines of weakness in said walls.

3. The method of claim 1 wherein said creasing step comprises the step of folding said first and second walls along fold lines pre-folded in said walls.

4. The method of claim 1 including the step of twisting a portion of said sleeve sufficiently to place said lines at opposed edges of the sleeve in said twisted portion.

* * * * *

United States Patent [19]

Juster et al.

[11] 3,934,721

[45] Jan. 27, 1976

[54] PACKAGED CATHETER ARRANGEMENT

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[22] Filed: Feb. 15, 1973

[21] Appl. No.: 332,584

Related U.S. Application Data

[63] Continuation of Ser. No. 149,990, June 4, 1971,
abandoned.

[52] U.S. Cl. 206/364; 128/349 R

[51] Int. Cl. A61b 19/02; A61m 25/00

[58] Field of Search. 128/348, 349 R, 350, 351;
206/63.2 R, 364

[56] References Cited

UNITED STATES PATENTS

2,863,453 12/1958 Gewecke 128/227

3,035,691	5/1962	Rasmussen et al.	206/63.2 R
3,112,031	11/1963	Stewart	206/63.2 R
3,169,527	2/1965	Sheridan	128/349 R
3,203,545	8/1965	Grossman	206/63.2 R
3,215,265	11/1965	Welin-Berger	206/63.2 R
3,606,001	9/1971	Talonn et al.	206/63.2 R
3,750,875	8/1973	Juster	128/349 R

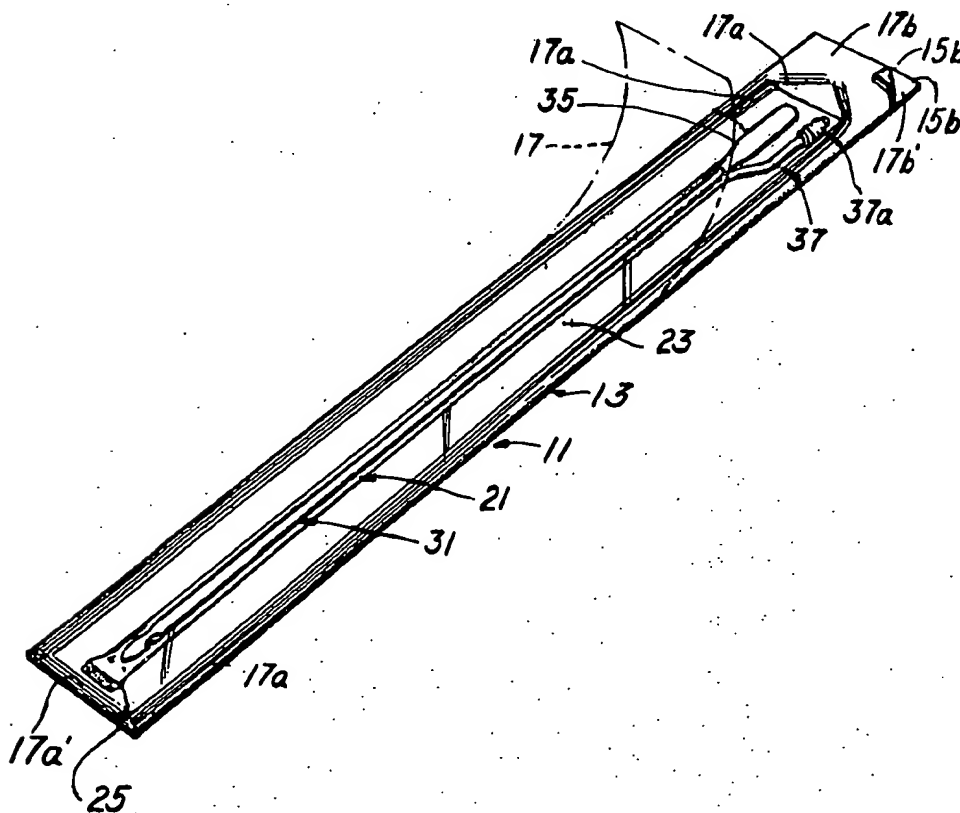
Primary Examiner—Dalton L. Truluck

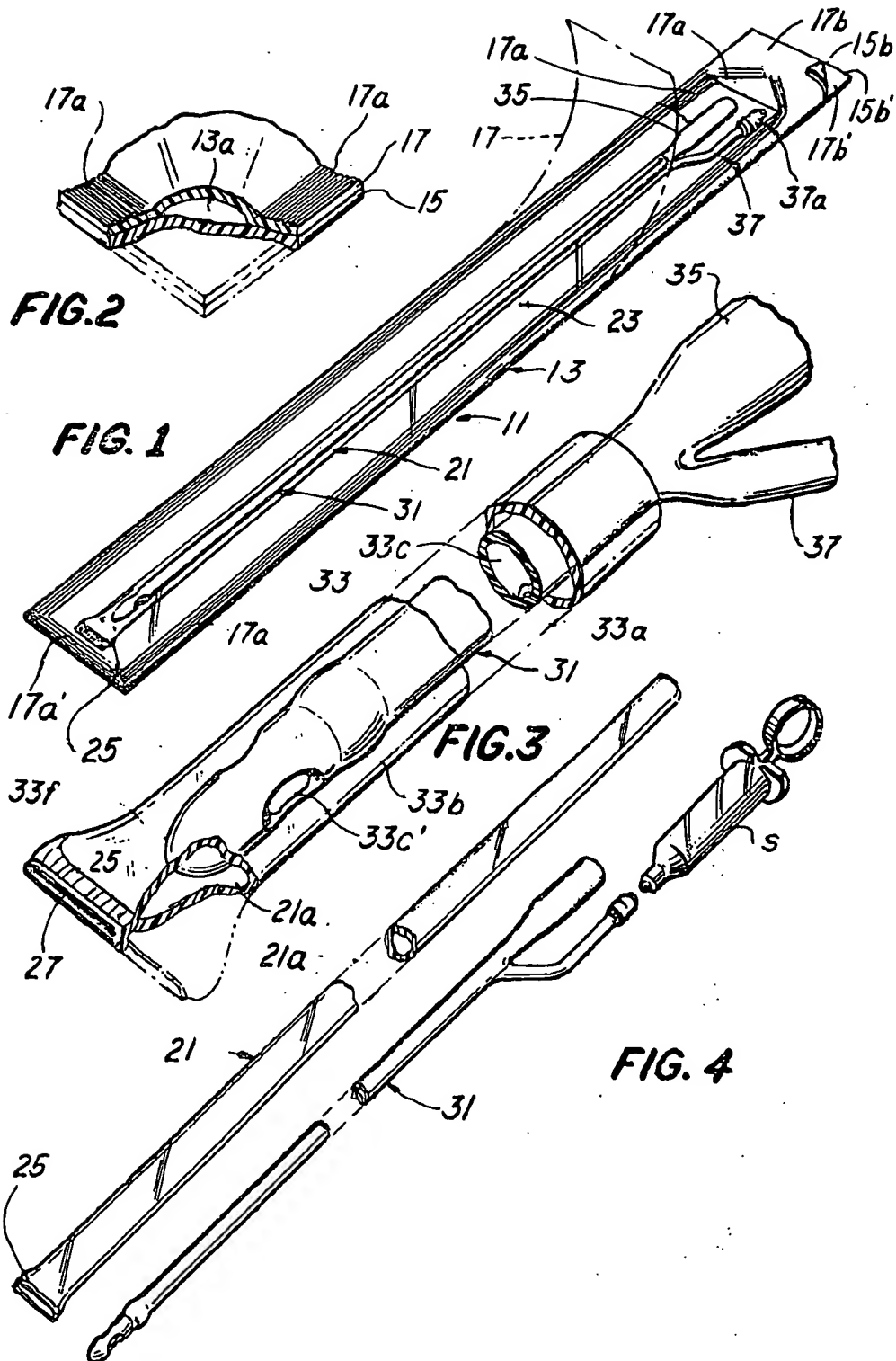
Attorney, Agent, or Firm—Reginald F. Pippin, Jr.

[57] ABSTRACT

A packaged catheter arrangement having a soft and pliable latex rubber catheter for body orifice use and having its shaft slidably removably disposed within a relatively rigid tube sheath of plastic to form a catheter handling assembly which is enclosed as a unit within a peripherally sealed peel-apart dual sheet overpackage. The tube sheath is sealed closed at one end and the catheter preferably has a pre-lubrication coating on its insertion shaft and enclosed within the closed-ended tube sheath.

9 Claims, 6 Drawing Figures





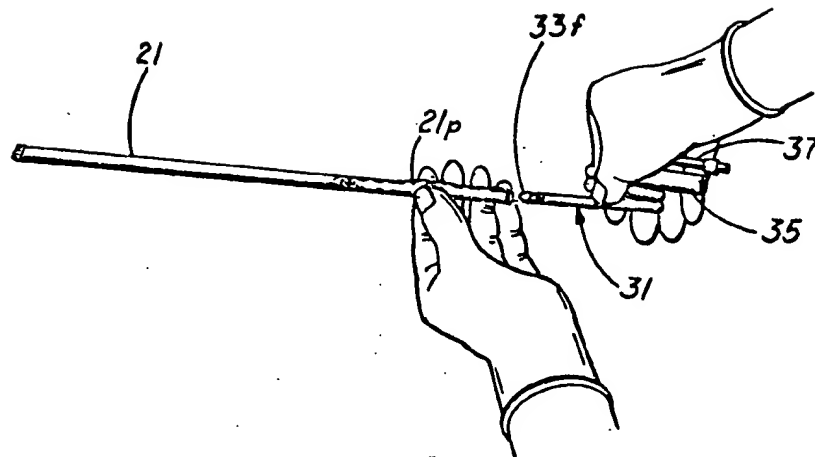


FIG. 5

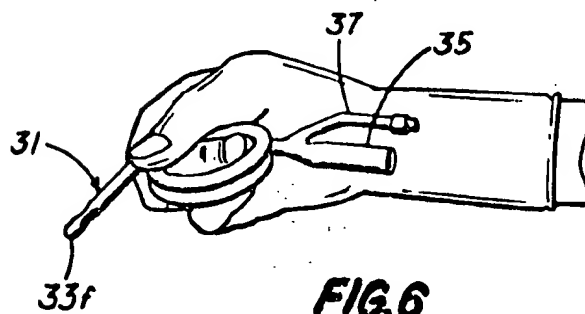


FIG. 6

PACKAGED CATHETER ARRANGEMENT

This application is a continuation of copending application Ser. No. 149,990, filed June 4, 1971, now abandoned.

This invention relates to an improved packaged catheter arrangement, and particularly to a packaged catheter arrangement which enables opening of the package and subsequent aseptic handling of the catheter in a mann that substantially reduces the likelihood of possible contamination of the catheter shaft prior to insertion into a patient.

It is conventional practice to furnish catheters in individual packages, so as to enable the catheters to be maintained in sterile condition until the desired time of use. Various packaging arrangements have been proposed and used for this purpose. It is a feature of the present invention to provide an improved packaging arrangement for point-of-use opening, and which enables subsequent rehandling of the catheter on a subassembly basis after opening of the overpackage, without seriously endangering the sterility of the catheter shaft.

It is a further feature of the invention to provide a package arrangement for catheters in which a catheter is reliably held in an extended position within a longitudinal overpackage, through the medium of a relatively rigid tube sheath which encompasses the insertion shaft of the catheter, thereby preventing the catheter from sliding down in the package and possibly kinking, and also making the catheter much easier to handle after removal from the overpackage, by grasping the tube sheath rather than the insertion shaft of the catheter.

Still a further feature is the provision of a catheter package arrangement which enables the packaging and storing until opening for use, of a catheter having a pre-lubricated shaft, while substantially obviating the normal likelihood of lubrication bleeding and staining of the outer package, and which further holds the catheter in a generally straight and unknicked packaged condition until removed for use, and which also enables controlled withdrawal of the catheter from a protective handling portion of the package arrangement.

Still other objects, features and attendant advantages will become apparent to those skilled in the art from a reading of the following detailed description of a preferred embodiment constructed in accordance with the invention, taken in conjunction with the accompanying drawings, wherein:

FIG. 1 is a perspective view illustrating a preferred embodiment of the invention.

FIG. 2 is a fragmentary view of one end corner of the package of FIG. 1.

FIG. 3 is an enlarged view of the assembled catheter and sheath assembly of FIG. 1.

FIG. 4 is an exploded view of the tubular sheath and catheter of FIGS. 1 and 3, together with a conventional syringe for catheter retention balloon inflation and deflation.

FIG. 5 illustrates the removal of the catheter from the tube sheath of FIG. 1, and the handling of the catheter by an operator during this removal operation.

FIG. 6 illustrates a further manipulated position of the catheter preparatory to patient insertion.

In the preferred embodiment as illustrated in FIG. 1, a catheter, generally indicated at 31, is inserted with its shaft 33 extending through a major extent of the length of a relatively rigid tube sheath 21, and the catheter 31

and tube sheath 21 are in turn contained within a peripherally sealed sterile zone pocket formed within an overpackage 13, thereby forming a complete package 11 of removable catheter and tube sheath unit 31, 21 contained within a sealed overpackage container 13.

The catheter 31 is merely an illustrative form of catheter, and may be of any suitable or desired catheter construction having a Y or other divergent fluid passage arm configuration. In the illustrative catheter construction, the catheter has the conventional form of a patient insertion shaft 33 with a drainage lumen 33c and drainage eye 33c', and connecting with a drainage arm 35, the catheter further having a branch arm 37 which is conventionally utilized for other fluid passage such as the passage of inflation fluid through a lumen 33a to and from a balloon section 33b spaced from the forward tip end 33f of the catheter shaft 33. Conventionally, the catheter is formed of soft latex rubber or other suitable soft, flexibly limber material, thereby providing a problem in packaging of the catheter so as to retain the shaft 33 in a desired generally straight condition from the time of packaging to the time of use. The present invention faciliates such a packaging and handling of the catheter 31.

Tube sheath 21 is formed of material which is relatively rigid as compared to the highly flexible and bendable soft latex rubber insertion shaft 33 of the catheter 31. It is desirable that the material be selected for the tube sheath 21 such that the tube sheath will self-retain and restore its own cylindrical tube form; yet be sufficiently elastically flexible to enable subsequent pinching of the tube shaft for control during removal of the catheter shaft 33 from the tube sheath, as will be later discussed. To this end, it has been found that a suitable material for the tube sheath 21 is extruded polyethylene tubing. As an example, a catheter having a shaft 13 of 1/4 inch O.D. has been assembled in a tube sheath of extruded polyethylene having an I.D. of approximately 9/32 inch, and a wall thickness of approximately 0.02-0.03 inch. The particular thickness, diameter, and clearance are not critical, so long as the desired rigidity is provided for a given tube sheath material, and provided that such clearance is provided between the catheter shaft and the inside of the tube sheath to enable the desired control and ease of assembly and disassembly of the catheter relative to the tube sheath. It is desirable that the tube sheath be translucent or transparent, as this provides aesthetic appeal to the overall package, although in some instances the tube sheath may, if desired, be formed of opaque or relatively opaque and/or colored material.

Tube sheath 21 is sealed across its free end, as by a transverse thermoplastic heat seal bond 25, which may be suitably effected as by a heated jaw clamp or by heated pressure rolls, or otherwise as may be desired. The closing of this end of tube sheath 21 aids in preventing the entry of foreign particles or other contaminant into the tube interior and preventing exit of material from within the tube, being of particular value in enabling the facile packaging of prelubricated catheters where shaft lubricant may tend to bleed or run to some extent.

The catheter 31 and the tube sheath 21 are disposed within the peripherally sealed pocket of the overpackage 13, with the closed end of the tube 21 adjacent one end of the longitudinal package, and the opposite open end of the tube sheath 21 and the extending arms 15, 17 of the catheter 11 disposed adjacent the opposite

closed end of the overpackage 13.

The overpackage 13 preferably takes the form of a sandwich of two peelably separable sheets 15, 17. The two sheets 15, 17 may be suitably formed respectively of a gas permeable paper base sheet 15 and a cover sheet 17 of interbonded mylar and polyethylene layers. The mylar-polyethylene cover sheet 17, which is preferably transparent except for such printing as may be placed thereon may itself be a bonded sandwich of an outer layer of mylar and a bottom layer of polyethylene, so as to provide the benefit of both materials, including the strength of mylar and the thermoplastic bonding and ease of sheet handling of polyethylene.

Prior to assembly of the catheter 31 and tube sheath 21 with the overpackage 13, the overpackage may be and is preferably partially pre-formed, by thermoplastic or other suitable peripheral bonding of the plastic cover sheet 17 to the paper base sheet 15, as indicated generally at 17a, preferably employing spaced multiple parallel seal lines to aid in preventing bacterial tunneling, and thereby providing a longitudinally extending central pocket sealed on three sides and with an open unsealed end at one longitudinal end of the dual-sheet overpackage. The assembled catheter 31 and tube sheath 21 may then be inserted through the open end of the pocket, to the position as shown in FIG. 1, and thereupon the previously open end may be sealed shut, as indicated at 17a', as by heat-sealing (preferably also multiple line spaced heat seals) of the thermoplastic cover sheet 17 to the paper base sheet 15 across this entire end. The entire package assembly 11, 21, 31 may then be subjected to gas sterilization, and if desired sterilization steps may be effected prior to or after various ones of the preceding assembly operations.

The peripheral seal zone of the overpackage 13, as provided by the seal lines 17a, 17a', provides an unsealed end flap zone 15b, 17b which may be easily separated and pulled apart as indicated at 15b', 17b' to peel the two sheets apart (note FIG. 1, in which the cover sheet is shown in phantom lines partially peeled away from the base sheet 17) and expose the catheter 31 and the tube sheath 21 for removal from the pocket 13a of the overpackage 13.

Upon peeling of the two sheets 15 and 17 apart, the operator may thereupon grasp the tube sheath 21 and remove the tube sheath and catheter assembly, preparatory to operator insertion of the tube sheath into a patient. In removing the catheter 31 from the tube sheath 21, the operator may proceed as illustrated in FIG. 5, grasping tube sheath 21 adjacent its open end with the normally contaminated gloved hand of the operator, while initially grasping the extended and exposed arm section 35, 37 with the opposite sterile gloved hand. In this respect, it will be appreciated that in the course of preparing the patient for catheterization the operator will have normally contaminated one gloved hand while leaving the other gloved hand sterile. The catheter 31 is then withdrawn from the open end of the sheath 21, and the operator may readily control this withdrawal by pinching the tube 21 to a desired extent, as indicated at 21p in FIG. 5, the catheter being indicated by broken lines in the process of being withdrawn from the tube sheath 21, and in full lines in a typical withdrawn position. Thus, a desired frictional retarding force is exerted on the catheter shaft 33 to prevent the shaft from uncontrollably and undesirably slipping out of the tube sheath 21 and striking a foreign object or falling on the floor prior to or while wrapping

of the shaft about the fingers of the operator to a position as shown in full lines in FIG. 5, preparatory to further manipulation of the catheter by the operator for insertion of the tip end 33f into a patient. After insertion of the shaft 33 into a patient the operator may then inflate the retention balloon 33b, as by inserting an inflation syringe 5, of conventional construction, into the inflation arm 37 and pumping fluid through arm 37 and lumen 33a to the balloon 33b. It will of course be apparent that the catheter 31 may be of any desired type or construction, and that the present illustration of a Foley-type catheter and inflation syringe 5 for use therewith is only by way of illustration of a typically packaged catheter according to the invention. Also, while one might package a syringe 5 with a catheter, such is not normally desirable, as the syringe may be reusable, whereas it is now the better practice to employ catheters on a single use basis.

From the foregoing discussion it will be apparent that through the employment of the novel catheter packaging arrangement according to this invention, a total packaging arrangement 11 is provided which facilitates assembling of the catheter within the outer overpackage, which maintains the catheter in a generally straight condition from point of packaging to end use, which provides protection for the sterile catheter shaft in case of undetected puncture of the outer overpackage 13, which facilitates the catheter removal from the outer package and subsequent handling of the catheter, such as illustrated in FIG. 6, preparatory to final operator insertion. In addition, the tube sheath materially aids in reducing the likelihood of lubricant staining of the outer package or bleeding of the lubricant from the shaft of a pre-lubricated shaft catheter through the outer package, thereby also better retaining the initial content of lubricant on the catheter shaft in view of the relatively nonporous and low absorption characteristic of the plastic tube sheath, particularly as compared to the paper sheet 17 forming a portion of the overpackage 13. In addition, the smooth extruded plastic tubular sheath reduces the likelihood of pick-up of fibrous or other foreign particles from the paper sheet 15 of the outer package, or from other fibrous or particle sheet material which may be employed, and particularly as has been employed in prior arrangements where cardboard stiffening insert sheets have been utilized to retain the catheter in some semblance of a desired straight configuration.

While the invention has been illustrated and described with respect to a particular illustrative and preferred embodiment, it will be appreciated that various modifications and improvements can be made without departing from the scope and spirit of the invention. For instance, the overpackage might take other forms than as illustrated, such as with both sheets, 15 and 17, being formed of paper. Accordingly, the invention is not to be limited by the particular illustrative embodiment, but only by the scope of the appended claims.

We claim:

1. A packaged catheter arrangement, comprising a flexible rubber catheter having an easily flexible insertion shaft with an insertion tip at one end and having two divergent fluid passage arms, a flexible tube sheath, the tubular extent and shape of said tube sheath laterally enveloping and serving to protect the length of said catheter insertion shaft during and subsequent to assembly as a dual com-

5

ponent unit of said packaged catheter arrangement,
 said tube sheath being closed at one end and open at
 its other end,
 the interior of said tube sheath being of a size to
 accommodate said catheter shaft, but insufficient
 to accommodate said two divergent fluid passage
 arms,
 and said catheter insertion shaft being removably
 disposed within said tube sheath with its insertion
 tip adjacent said closed end of said tube sheath and
 having its two divergent fluid passage arms adja-
 cent and extending beyond said open end of said
 tube sheath.

2. A packaged catheter arrangement according to
 claim 1,
 one of said divergent fluid passage arms being an
 inflation arm disposed adjacent and extending be-
 yond said open end of said tube sheath.

3. A packaged catheter arrangement according to
 claim 1,
 said closed other end of said tube sheath having a
 heat seal crimp extending transversely thereof.

4. A packaged catheter arrangement according to
 claim 1,
 said catheter insertion shaft being coated with a lu-
 bricating medium, and said coated insertion shaft
 being enclosed within said tube sheath.

5. A packaged catheter arrangement according to
 claim 1,
 said catheter having a further fluid conducting arm
 extending beyond said tube sheath.

6

6. a packaged catheter arrangement according to
 claim 1,
 and a flexible overpackage surrounding said entire
 catheter and tube sheath and being closed there-
 around.

7. A packaged catheter arrangement according to
 claim 6,
 said flexible overpackage comprising a base of fi-
 brous sheet material and a cover sheet of light-
 transmitting see-through plastic peripherally
 bonded to said base sheet about said catheter and
 tube sheath to form an enclosed loose pocket or
 cavity for said catheter and tube sheath,
 said cover sheet being removably peelably separable
 from said base sheet, and said sheets having un-
 bonded tab ends at one end of said overpackage for
 ease in separating said sheets to remove said cathe-
 ter and tube sheath therefrom.

8. a packaged catheter arrangement according to
 claim 7,
 said sheets having a peripheral heat seal bond.

9. A packaged catheter arrangement according to
 claim 1,
 said flexible tube sheath being substantially more
 rigid than said catheter insertion shaft and serving
 the dual function of protecting and rigidifying the
 length of said insertion shaft and presenting said
 two divergent passage arms in open accessible ex-
 tended relation beyond the adjacent open end of
 said tube sheath.

* * * * *

O. B. SCHELLBERG.
CATHETER CASE.
APPLICATION FILED DEC. 18, 1913.

Patented Dec. 8, 1914.

1,120,549.

Fig. 2.

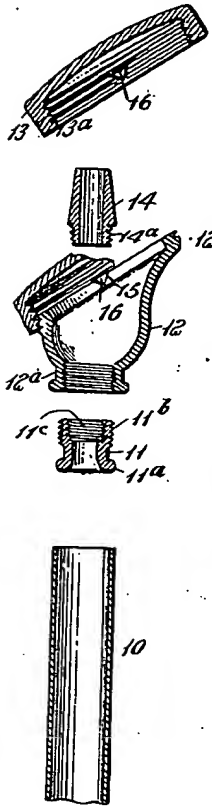


Fig. 1.

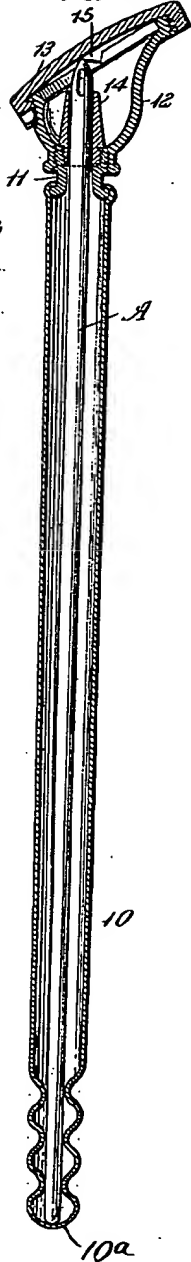


Fig. 3.

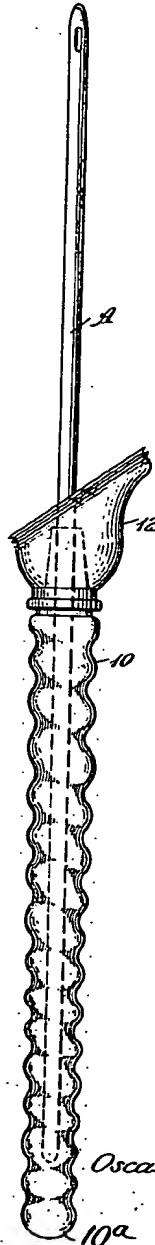
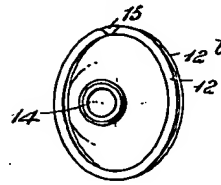


Fig. 4.



WITNESSES

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INVENTOR

Oscar B. Schellberg

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M. W. Jones
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UNITED STATES PATENT OFFICE.

OSCAR B. SCHELLBERG, OF NEW YORK, N. Y.

CATHETER-CASE.

1,120,549.

Specification of Letters Patent.

Patented Dec. 8, 1914.

Application filed December 18, 1913. Serial No. 807,441.

To all whom it may concern:

Be it known that I, OSCAR B. SCHELLBERG, a citizen of the United States, and a resident of New York city, borough of Bronx, in the county of Bronx and State of New York, have invented a new and Improved Catheter-Case, of which the following is a full, clear, and exact description.

My invention relates to a novel container or case to hold a catheter, and an object of my invention is to provide a case in which the catheter may be inclosed and the whole subjected to a sterilizing heat whereby the catheter will be effectively sterilized and may be maintained and carried in a sterilized and aseptic condition until required for use.

A further object of my invention is to provide a container case for the instrument from which the latter may be projected and then be fully entered in the urethra and manipulated to draw off the urine, without exposing it to the atmosphere and without the surgeon or other operator directly handling the instrument. Thus all danger of the instrument becoming contaminated by contact with the user's fingers is obviated. The container case, in addition to being designed to be of a character to be utilized by the operator in manipulating the instrument in entering the latter into the urethra, is further designed to permit of restoring the instrument to the container to be again sterilized while inclosed, without the necessity of the operator at any time bringing the instrument into direct contact with the fingers.

In carrying out the invention, use is made preferably of flexible rubber to form an elongated, collapsible body to accommodate the catheter, said body having an integral, closed bottom end, and fittings are provided for the open upper or front end. The fittings, in their entirety, comprise a cover to constitute a hermetic closure, a member receiving the cover and advantageously shaped with regard to the terminal conformation of the organ to receive the instrument, and a guide neck to facilitate the proper entrance of the instrument to the urethra, the elements thus included possessing their individual advantages and being coöperatively arranged when the case is provided with all of said elements, as in the preferred embodiment.

The invention will be particularly explained in the specific description following.

Reference is to be had to the accompanying drawing forming a part of this specification, in which similar characters of reference indicate corresponding parts in all the figures.

Figure 1 is a longitudinal, sectional view of the complete device; Fig. 2 is a longitudinal section showing the elements separately, part of the body of the case being broken away; Fig. 3 is a side elevation showing the catheter partly projected from the casing, the cover having been removed; and Fig. 4 is a front end view of the device with the cover removed.

In forming a case or container in accordance with the illustrated practical embodiment, an elongated body 10 of general tubular form is made from flexible rubber or equivalent flexible waterproof and airproof material, the rear or bottom end 10^a being closed and integral with the body. The body as thus formed is essentially a flexible sack, and has a length to accommodate the catheter A; or the major portion thereof, and is freely collapsible in all directions.

To the open front end of the body or sack 10, a neck 11 is hermetically joined, through which the instrument may be passed into and out of the body. Primarily, means is provided for the reception of a cover to hermetically close the open end of the tubular body 10. In the example shown, the neck has a bead 11^a over which the upper end of the rubber is stretched, and an external thread 11^b on the neck, at the upper end, receives the interiorly threaded lower end 12^a of a flaring extension 12. The open upper end of the extension 12 receives a cover 13, the extension and cover having mating threads 12^b, 13^a, and the two constituting a cap to form a hermetic closure of the body.

It will be observed that the extension 12 at the front end is inclined to the axis of the body 10 and neck 11, and that the said neck is thus disposed eccentrically with the extension, its axis being at one side of the center of the extension. The laterally inclined terminal edge of the extension 12 and its described arrangement relatively to the neck 11 is to conform the device to the position of the urethra and the adjacent anatomical conformation, whereby the extension constitutes a means to locate and position the device.

In connection with the neck a guide tip 14 is provided and, in the preferred con-

struction, it is detachable from the neck, being formed with an external thread 14^a which takes into an internal thread 11^a on said neck. The central bore or passage through the guide tip forms a continuation of the bore or passage of the neck, the outer end of the tip desirably terminates just within the inclined-edge portion of the extension 12.

When the catheter A is within the case and the latter closed by the cover 13, or equivalent closure, it will be apparent that the complete article may be subjected to heat by submerging it in water of the required temperature, or other approved treatment, to sterilize by heat. The inclosed instrument will thus be preserved in aseptic condition and may be carried in the pocket or satchel ready for use without further sterilization.

To use the catheter, the cover 13 is removed and the inclined front of the extension 12 is so positioned that the tip 14 will be in line with and adjacent to the entrance to the urethra. The operator, while grasping the flexible sack 10, gradually enters the instrument and relatively works the sack rearwardly until it is finally slipped from the rear end, with the instrument free to constitute a duct for the fluid discharge.

It will be noted that not only is the instrument inserted without being directly grasped, with the liability of contamination from the fingers, but its exposure to the atmosphere with the possibility of contamination therefrom, is either wholly avoided or reduced to a minimum.

Upon completion of the operation, the instrument, after being washed if desired, may be placed in its case by an obvious manipulation of the latter, to be again sterilized while inclosed, and be thus available in aseptic condition whenever required.

The extension 12 has a notch 15 in the edge thereof, constituting a lateral opening. The cover 13 has a lateral opening 16 outward from the edge and registering with the opening 15 when the cover is partially turned. Thus the threads 13^a at the edge of the cover will engage threads 12^b below the opening 15, and hold the cover in place with the openings in register, for draining off the boiling water or other sterilizing fluid without fully removing the cover.

Having thus described my invention, I claim as new and desire to secure by Letters Patent:

1. A combined catheter and a case to protect and manipulate the same, comprising a catheter, a container consisting of an elongated hermetic body having an open forward end provided with a neck in which the catheter has a guided fit, and a removable

closure for the said open end, the said body being flexible and adapted to collapse as the catheter is forced outward through the said neck.

2. A container of the character described comprising an elongated, collapsible body to receive the catheter, the mouth of the container having a fitting provided with a closure and an annular member surrounding the mouth, the outer edge of which is inclined to the axis of the body.

3. A container of the character described comprising an elongated body having an open end for the insertion and removal of a catheter, and an annular element surrounding the open end and open for the passage of the catheter to and from said open end, the outer edge of said element being inclined in a plane at an angle to the axis of the body.

4. A container of the character described comprising an elongated body adapted to receive a catheter, and a fitting on an open end of the container, said fitting forming a neck presenting a passage for the entrance and removal of the catheter, and an annular element surrounding the neck and concentric therewith.

5. A container of the character described having an elongated body adapted to receive an instrument, and a fitting at an open end of the body, said fitting consisting of a neck having a forwardly projecting guide tip for the entrance and removal of an instrument to and from the body, and an enlarged annular member outside the guide tip and concentric therewith, the outer edge of the said member being in a plane inclined to the axis of the tip and neck.

6. A container adapted to hold a surgical instrument and provided at the mouth thereof with a threaded annular member, formed with a lateral opening in the edge thereof, for draining off a sterilizing fluid, and a closure having a lateral opening outward from the edge to register with that of the said member when the closure is partially removed.

7. An aseptic hermetic container and manipulating protector for catheters, comprising an elongated flexible aseptic body having an open end formed with a neck affording a guiding fit for a catheter, and means independent of said neck to effect a closure of said open end.

In testimony whereof I have signed my name to this specification in the presence of two subscribing witnesses.

OSCAR B. SCHELLBERG.

Witnesses:

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United States Patent

Jackson

[15] 3,648,704

[45] Mar. 14, 1972

[54] DISPOSABLE CATHETER APPARATUS

[72] Inventor: Frederick E. Jackson, 1762-B Marine Corps Base, Camp Pendleton, Calif. 92055

[22] Filed: July 17, 1970

[21] Appl. No.: 55,769

[52] U.S. Cl. 128/349 R, 206/63.2 R

[51] Int. Cl. A61m 25/00

[58] Field of Search.....128/348, 349 R, 350 R, 260, 128/261, 239; 206/63.2 R

[56] References Cited

UNITED STATES PATENTS

3,175,553	3/1965	Mattson.....	128/2
3,154,080	10/1964	Rowan et al.	128/349 R
2,856,932	10/1958	Griffitts.....	128/349 R X
3,474,786	10/1969	Spademan	128/214.4
3,556,294	1/1971	Walck et al.	206/63.2 R

3,345,988	10/1967	Vitello	128/349 R
3,444,860	5/1969	Harrell.....	128/349 R

Primary Examiner—Dalton L. Truluck

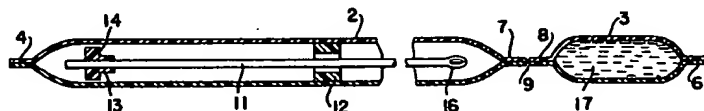
Attorney—R. S. Sciascia and Paul N. Critchlow

[57]

ABSTRACT

A urethral catheter tube formed of a flexible low-friction plastic is carried in a transparent plastic casing one end of which is flattened and severably joined to a plastic cap member. The other end of the casing is closed to form a reservoir. The cap member is a closed vessel containing a lubricant. When the cap is separated from the casing it can be opened to permit application of the lubricant and the casing also opened to permit insertion and implantation of the catheter. Both the lubricant and the catheter tube can be maintained in a sterilized condition and the catheter remains sterile during implantation since it can be worked out of the casing by aseptically contacting it through the casing walls, the net result being that the catheter need not be contacted by human hands.

10 Claims, 4 Drawing Figures



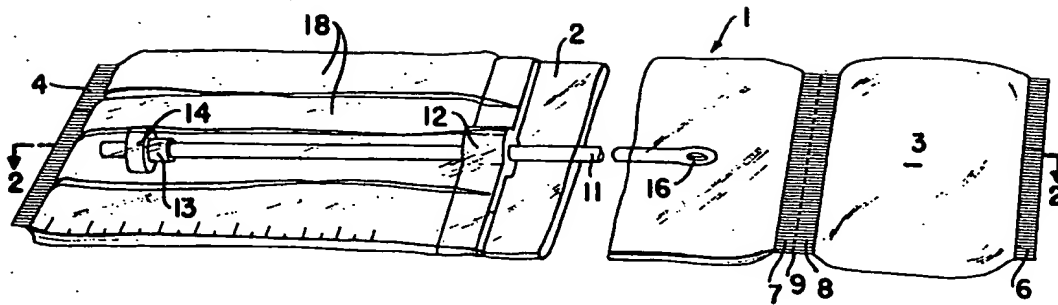


FIG. 1

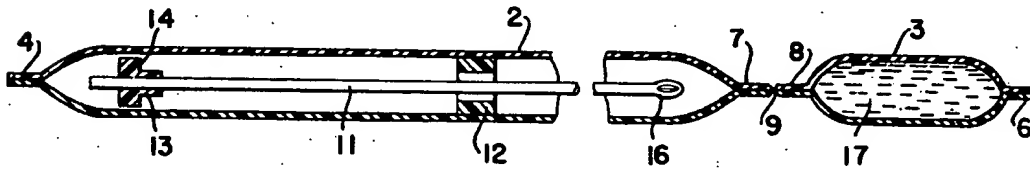


FIG. 2

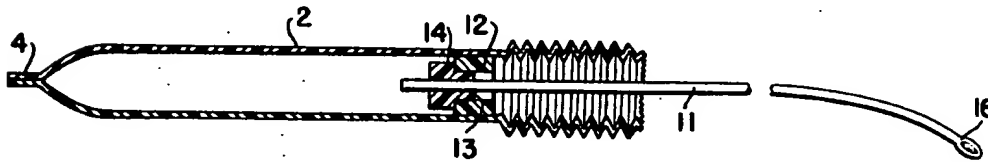


FIG. 3



FIG. 4

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DISPOSABLE CATHETER APPARATUS

The invention described herein may be manufactured and used by or for the Government of the United States of America for governmental purposes without the payment of any royalties thereon or therefor.

BACKGROUND OF THE INVENTION

The present invention relates to disposable catheters and, in particular, to sterile catheter apparatus which can be applied manually without direct contact by human hands or other unsterile objects.

Many hospital patients require urethral catheterization and one of the serious problems in the treatment of these patients is to prevent urinary infections. Infections, however, can be substantially reduced by limiting the period of time in which the catheter remains in place or, in other words, by employing an intermittent rather than an indwelling technique. Even so, the intermittent technique presents real problems that have greatly restricted its obviously beneficial use. The principal problem arises because of the relative frequent need for catheterization coupled with the requirement that each operation must be conducted with sterile equipment and by trained personnel to assure aseptic cleanliness. These requirements apparently have proven too demanding particularly for hospitals or clinics which are notoriously overcrowded and understaffed.

However, there have been several prior art arrangements which utilize disposable catheters that can be handled aseptically. The aseptic handling is achieved by enclosing the catheter tube in an envelope in such a manner that the tube can be inserted by retracting the envelope while pressing the tube in an outward direction. Since the tube itself is not directly touched, it remains sterile. Also, the disposability of the entire arrangement avoids the need for resterilization.

Such prior art arrangements clearly are advantageous, although unfortunately they have not been adapted and used to any appreciable extent. Apparently the reason for their low use has been that the specific arrangements have been rather impractical, difficult to use and relatively expensive. Further, they do not provide in one unitary package all of the necessary components and materials such, for example, as a sterile lubricant to facilitate insertion or a convenient receptacle for collection of the samples. The need is to provide a catheter package that can be distributed economically to patients with assurance of convenient, noninfectious use as the occasion arises.

OBJECTS OF THE PRESENT INVENTION

It is, therefore, one of the objects of the present invention to provide a low cost, disposable catheter apparatus including a catheter tube capable of being aseptically handled, a lubricant and a convenient receptacle for collection of samples through the implanted catheter tube.

Another object is to provide a convenient and relatively inexpensive packaging arrangement for such catheter apparatus, the convenience permitting use by relatively untrained personnel.

A further more specific object is to provide a packaging arrangement in which the lubricant and the catheter tube are separately sealed in their own containers which, in turn, are joined so that separation of the two containers permits both to be opened for use.

Another specific object is to provide catheter apparatus in accordance with the foregoing objects, the container of the catheter tube also providing a receptacle for sample collection.

These and other objects which will become more apparent are achieved by providing apparatus including a flexible, transparent, open-ended tubular casing that encloses an elongate flexible catheter tube. One end of the casing is closed to provide a baglike receptacle for sample collection through the tube after it has been implanted. The other end of the casing is joined to a cuplike capping member and, preferably, the

joined ends of the casing and the capping member both are constricted or pinched together for sealably closing the interiors of each of the members. A lubricant or other catheterizing material is contained in the cuplike member and the sealing of this member, as well as the casing member, permits the contents of both of these members to be maintained in a sterilized condition. Separation of the two members permits both to be opened and the contents exposed for use. The caplike member can be squeezed to apply lubricant, while the casing member can be manipulated to progressively work the catheter tube outwardly from the casing to permit its insertion and implantation. The lack of any direct contact by human hands of the tube itself maintains a sterile, aseptic condition of the tube and, most suitably, the extent to which the tube can be worked out of the casing is limited so that a length of the tube remains in the casing to provide a communication between the body cavity and the receptacle portion of the casing.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is illustrated in the accompanying drawings of which:

FIG. 1 is a face view showing the transparent package or casing of the catheter apparatus and certain of the components contained in the package;

FIG. 2 is a longitudinal section taken along lines 2-2 of FIG. 1;

FIG. 3 is a section similar to FIG. 2 of the catheter tube portion of the apparatus; and

FIG. 4 is a perspective illustrating the capping member and the manner in which it is used.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 2, the catheter apparatus is shown enclosed in a transparent, plastic envelope or package generally indicated by numeral 1, the envelope being formed of an elongate casing member 2 and a capping member 3. Ends 4 and 6 of the envelope both are closed by any appropriate means, such as by heat-sealing, so that, in effect, both casing member 2 and capping member 3 are provided with closed ends permitting both of these members to be used as containers in a manner which will be described. The other ends 7 and 8 of the casing and capping members are joined together in such a manner that each of the members forms a separate container. More specifically, end portions 7 and 8 are compressed and separably joined again by a heat-sealing process or the like. To permit separability of the casing member and the capping member, the joined portions of these two members may be scored, perforated or otherwise weakened so that the two members readily can be separated by tearing. Alternatively, a tear strip can be employed although obviously the tear line must not sacrifice sealability which, in turn, assures sterility. The rip or tear line for the members is indicated by numeral 9 of FIG. 1.

Casing member 2 sealably encloses an elongate catheter tube 11 as well as a lock ring 12 which, for reasons to be set forth, is provided to restrain the extent to which catheter tube 11 can be worked outwardly of its casing or, in other words, to assure that a portion of the catheter tube remains within casing 2. A sleeve or ferrule 13 mounted on the trailing end of catheter tube 11 cooperates with lock ring 12 to achieve the desired restraining action. As shown, ferrule 13 is fixedly mounted on the end portion of tube 11 and the ferrule is formed with a reduced diameter portion adapted to fit within the internal diameter of ring 12, the remainder of the ferrule being enlarged so as to provide a flange 14 which abuts ring 12 and restrains further outward movement of the tube. Ring 12 also is fixedly mounted by being joined in an appropriate manner to the plastic casing member.

Catheter tube 11 may be of any conventional type although preferably it should be formed of a smooth-surfaced silastic material which is of low friction material adapted to facilitate use of the tube. Also to facilitate use, the tube should be flexi-

ble although a certain degree of stiffness is needed to assure insertion. In this regard, it no doubt is apparent that the present apparatus primarily is intended as an urethral catheter although the packaging arrangement could with certain modifications be adapted for other catheterizing applications. As an urethral catheter, the tube is hollow and open-ended, the leading end of the tube being slightly enlarged and provided with particular opening 16 which permits flow from the bladder through the tube into the casing.

Cap member 3 provides a separate container coupled to casing member 2 in the manner already described, this member being used to provide a lubricating material facilitating the insertion of catheter tube 11. More specifically, cap 3 is filled with a lubricant 17 which, when the cap is separated from casing member 2 becomes available for use both on the tip of catheter tube 11 and around the entrance to the urethral passage.

Other features of the invention best can be appreciated by considering the manner in which the present catheter apparatus is used. In fabricating the apparatus, the catheterizing components such as tube 11 and lubricant 17 are enclosed in envelope 1 and the envelope heat sealed to provide a tight closure which then can be sterilized in any suitable manner to maintain these components in an aseptic condition. The packaged apparatus then may be marketed, stored and distributed as sterile packages and the notation "STERILE" can, if desired, be marked on the exterior of the package. Also, distribution of the packaged apparatus either can be to hospital personnel trained to perform the catheterizations or relatively untrained personnel, such as patients themselves, can perform the task with very little preliminary instruction. When catheterization is required, the user simply separates the cap member from the casing member by ripping the package along line 9 and the separation causes ends 7 and 8 of these members either to open or to be readily openable. The first step, as has been indicated, is the application of sterile lubricant 17 and, as desired, the lubricant can be applied both to end 16 of the tube and to the urethral passage. Preferably, application of the sterile lubricant to the end of the tube is accomplished as soon as the tip end is exposed, although it may be desirable to apply a small amount of the sterile lubricant to end 7 of casing member 2 prior to initial exposure of tip 16. The manner in which lubricant 17 is applied is illustrated in FIG. 4 where it will be seen that application can be accomplished simply by squeezing cap member 3 to extrude whatever amount of lubricant may be required. Obviously, it is desirable that lubricant 17 be somewhat viscous so that a squeezing action is required for the application.

In a manner intended to be illustrated by FIG. 3, catheter tube 11 can be progressively inserted into the urethral canal for implantation in the bladder of a patient without directly contacting the tube with human hands or other instruments which might produce contamination and destroy its aseptic condition. More specifically, the tip portion of tube 11 can be exposed by grasping the tube through package 2 and moving the tube relative to the package to cause tip 16 either to break through the closed end of the package or, if this end is already open, to pass through the opening. Tip 16 then is inserted in the urethral passage and the tube progressively worked into implanted disposition by gently continuing the forward thrust of the tube relative to casing member 2, the casing member being retracted in the manner shown in FIG. 3 as the progressive insertion is accomplished. The tube, of course, is of sufficient length to extend fully into the bladder of the patient and, when so implanted, the tube may be locked in position by retracting the casing to contact its ring 12 with locking ferrule 13. The apparatus then is in position to receive urine samples which pass through the tube into the rearward portion of the casing, this rearward portion preferably being provided with longitudinal pleats 18 (FIG. 1) to provide a baglike reservoir to receive the sample.

Another distinct advantage of the present apparatus is that it can be manufactured relatively inexpensively and that its

components also can be made from inexpensive materials, these features provide a total package which permits disposability after each use without any particular economic sacrifice. In this regard, it has been pointed out that the present catheter is intended for intermittent catheterizations as opposed to the more conventional indwelling Foley-type catheters which, as has been demonstrated in practice, are far more prone to produce infection due entirely to the period of time in which they remain implanted. The particular advantages of the present apparatus are found in the ability to handle the catheter tube aseptically so as to avoid the need for sterilizations or resterilizations upon each use or reuse. Disposability obviously avoids the prior need for resterilization. In addition, the apparatus includes all of the elements necessary for intermittent catheterization, these elements, in addition to the catheter tube itself, being the ready availability of lubricant 17 as well as the availability of a baglike reservoir portion of the casing as a sample collector. A further refinement of the apparatus is to mark the pleated portion of the casing in graduated cubic centimeter indices to provide a visual indication of the volume of the sample. In total, a complete catheterizing package is provided which can be conveniently and easily used in a safe and reliable manner and which, after collection of a sample from its receptacle portion, can be disposed of at minimum expense.

Obviously many modifications and variations of the present invention are possible in the light of the above teachings. It is therefore to be understood that within the scope of the appended claims the invention may be practiced otherwise than as specifically described.

I claim:

1. Disposable catheter apparatus comprising:

a flexible transparent elongate open-ended tubular casing member having one of its ends closed for providing a baglike receptacle portion,

an elongate flexible catheter tube longitudinally disposed within said casing,

a cuplike open-ended capping member having its open end portion sized to match the open end portion of said casing member,

fluid catheterization material carried by said capping member,

the open ends of the casing and capping members being pressed together to provide a flattened sheetlike multi-ply section common to both members and said section having its plies severably united for sealably closing both of said members,

whereby the contents of said members can be maintained in a sterilized condition and the catheterization can be conducted by separating said members and reopening said open ends,

the reopening permitting said sterilized fluid material to be applied for catheterization and said sterile catheter tube to be worked out of said casing for implantation by aseptically manipulating the catheter tube through contact with the casing, said envelope then providing a baglike reservoir for receiving fluids delivered through the implanted catheter tube.

2. The apparatus of claim 1 further including means for positively retaining a portion of the tube within the casing whereby the retained portion provides a conduit communicating with said baglike receptacle.

3. The apparatus of claim 2 wherein said retaining means includes a ferrule fixedly disposed interiorly of said casing and a flanged lock ring carried by said catheter tube, said lock ring mating with said ferrule whereby said flanged portion restrains movement of the tube outwardly of the casing.

4. The apparatus of claim 2 wherein said catheter tube is formed of a smooth low-friction plastic.

5. The apparatus of claim 4 wherein said fluid material is a lubricant adapted to be applied to the catheter tube and the patient for facilitating catheterization.

6. The apparatus of claim 2 wherein said baglike receptacle portion of the casing is expandable to increase its capacity.